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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,884	01/24/2000	Lori Lisa Carrigan	1204	7780

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/27/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/490,884

Applicant(s)

CARRIGAN, LORI LISA

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 21-30, 34, 35, 37-42, 47 and 52-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7, 21, 23, 24, 26 and 40 is/are allowed.
- 6) ☒ Claim(s) 6, 9-16, 22, 25, 28-30, 34, 35, 37-39, 41, 42, 47 and 52-75 is/are rejected.
- 7) ☒ Claim(s) 8 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejections of claims 22, 30-33, and 47-49 under 35 U.S.C. 112, 2nd paragraph, are withdrawn, in light of the claim amendments or cancellations.
3. The rejection of claims 9, 10, 14, 17, 22, 28, 29, 32, 33, 36, 41, and 43 under 35 U.S.C. 102(e)/103(a) is withdrawn, upon further consideration.

Claim Objections

4. Claims 8 and 27 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Both claims attempt to limit the method of the claim from which they depend by requiring the PH51H plant, or the plant of claim 21, to be either the female or male parent. However, there are no other choices encompassed by claims 7 and 26.

Claim Rejections - 35 USC § 112

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5. Claims 6, 11-13, 15, 16, 25, 34, 35, and 52-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 6 and 25: the recitation "capable of expressing" in line 2 renders the claims indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation be replaced with the recitation, --said plant having--.

In claim 11: the recitation, "comprises contains" in line 3 renders the claim indefinite. It is not clear what this recitation encompasses. NOTE: this claim was not labeled as "Currently amended" in the paper submitted 12 June 2003. However, the claim differs from the amended claim as it is written in the paper submitted 13 December 2002, in the noted recitation. Claim 11 is therefore being treated as a currently amended claim.

In claims 15 and 34: the claim is indefinite because the last step of the claim is inconsistent with the preamble. The first line of the claim indicates that the method is for developing a maize plant in a maize plant breeding program. However, the last step is for employing the plant of claim 2 or 21, or parts thereof, as a source of breeding material. It is not clear how a maize plant is to be developed in a maize plant breeding program.

In claims 52, 57, 62, 66, and 71: the recitation "A method of making a PH51H plant" in line 1 of the claims renders them indefinite. However, the method cannot make a PH51H plant, since it comprises introducing a gene into PH51H. This plant is part of the starting material, not the product.

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In claims 55, 60, 64, 69, and 73: the recitation "comprising the method of claim 52 (or 57 or 62 or 66 or 71) and further comprising crossing the PH51H maize plant of claim 52 with a second maize plant" renders the claim indefinite. If the method comprises crossing PH51H with a second maize plant, it is not clear how the method of claim 52 is involved.

In claim 68: the recitation "a cytoplasm that confers male sterility" in line 3 renders the claim indefinite. It is not exactly clear what is encompassed by the recitation. The metes and bounds of the claim are not clear.

6. Claims 9-16, 22, 28-30, 34, 35, 37-39, 41, 42, and 47 remain and new claims 52-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 12 March 2003 under item 6. Applicant traverses the rejection in the paper filed 12 June 2003. Applicants' arguments were fully considered but were not found persuasive.

Applicant argues that the F1 hybrid seed and plant produced using PH51H, regardless of the other maize plant used, is identifiable because it will have a single set of individual chromosomes coming from PH51H. Applicants also argue that one would be able to run a molecular profile on PH51H and the F1 hybrid to identify the hybrid as being produced from PH51H (response, paragraph bridging pages 12-13, page 13, 1st full paragraph, and paragraph bridging pages 13-14). However, as discussed in the previous Office action, no information is

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described about SSRs or other genetic markers of PH51H. Further, the traits associated with any markers are not described.

Applicant argues that claim 14 has been amended to provide sufficient description to evaluate the presence of claimed traits (response, page 13, 2nd full paragraph). The claim has been amended to require the presence of all of the listed traits, rather than only "at least two." However, the specification does not describe any such claimed plants having all of the listed traits. For example, the specification does not describe F1 or F2 progeny which have the hybrid yield trait (as opposed to yield of the F1 or F2 itself) of PH51H. The specification indicates that inbred PH51H hybrids demonstrate significantly higher yields than PHTD5 hybrids (page 35, lines 30-31). However, the claimed plants are themselves hybrids. The specification does not describe the yield of progeny of any hybrids.

Applicant argues that claims 15 and 16 are to a method of making a maize plant through the utilization of PH51H, and that an old process performed with a novel material is novel in and of itself, and cite the Federal Register, Vol. 66, No. 4, in support (response, page 13, 2nd full paragraph). However, the method of claims 15 and 16 involved the utilization of descendants of PH51H, which are not described. Methods are not described if products utilized in the methods are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

Applicant also cites a prior art reference, Openshaw et al., for noting that, by using molecular markers, one may obtain 98% or greater genome identity between backcross conversion and recurrent parent after two backcrosses (response, page 14, 1st full paragraph). However, Table 1 in the reference appears to indicate that only 87.5% of the recurrent parent genome is recovered after two backcrosses, and only assuming that there is no linkage to the

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gene being transferred. Further, the results referred to by Applicants were of computer simulations. Real field data showed that the recovery of the recurrent parent was lower after two backcross generations (page 42). Furthermore, the computer simulations of Openshaw et al. assume the absence of linkage of the allele being transferred from the donor parent. Moreover, even if 98% genome identity were obtained between the backcross conversion and recurrent parent, the remaining 2%, given the size of the maize genome, would encode traits not described by the specification. The specification also does not describe other nonselected traits and genes transferred during the first cross, and which are not selected out. Furtherstill, the instant disclosure did not describe any molecular marker data for PH51H at the time of filing. Applicant cites Wych for teaching that the backcrossing has been used since the 1950s, and Poehman et al. for teaching that a backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene (response, page 14, 1st full paragraph). However, neither reference indicates that the plant comprising the single gene conversion retains the traits of the recurrent parent that distinguishes it from other plants.

Regarding position that the molecular profile of PH51H is not described in the specification, Applicant argues that, as described on page 15, lines 2-29, the seed deposit allows one of ordinary skill to run a molecular profile of PH51H (response, paragraph bridging pages 14-15). However, methods to obtain molecular markers do not describe the markers themselves. Applicants continue, arguing that an SSR profile is an inherent feature of inbred line PH51H, and cite *Ex parte Marsili*, *Rosetti*, and *Pasqualucci* in support (response, paragraph bridging pages 14-15). However, the issue in *Marsili* is not analogous. On page 905 of *Marsili*, the Court states that the amendment in *Marsili* was not new matter because it merely constituted a correction of a

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previously submitted description of a compound, which is permissible. Here, SSR would not merely be a correction of existing data, but would represent new characteristics. In *Marsili*, the specification disclosed a chemical structure for a compound, and the amendment merely corrected an error in the structure. In the instant case, no SSR data was present in the original specification, and introduction of such data would be new matter.

Applicants also argue that the test of written description is not whether the morphological and physiological traits of the PH51H progeny are described, but whether subject matter was described in such a way to convey to one of ordinary skill in the art that the inventor had possession of the claimed invention. Applicants continue, arguing that while PVP is distinct from patents, the scope of protection conferred by PVP provides a clear indication that breeders of ordinary skill in the art consider mutations, F1 hybrids, backcross conversions, and transgenic conversions to be within the scope of the invention of the variety itself. The fact that the progeny have not been created does not prevent them from being protected in this manner (response, page 15, last paragraph). However, the originally filed specification only describes PH51H by way of its morphological and physiological traits, and by way of deposit of PH51H seed, not its genotype. As information concerning the genome of PH51H was not known at the time of filing, molecular information cannot be used to describe progeny of PH51H. Further, as Applicant admits, the requirements for PVP and patentability are distinct.

Regarding claims 37-39, Applicant argues that the claims are directed to growing out F1 hybrid in which PH51H is a parent and searching for PH51H inbred seed, and that the claim is described in the specification on pages 5-6 (response, page 16, 1st full paragraph). However, as

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discussed above, the claims are included in the rejection because the method encompasses the use of products that are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

Regarding new claims 52-75, Applicants argue that the claims are drawn to methods and to the products produced by those methods, and are further limited by specified traits conferred by mutant genes or transgenes, examples of which are in the specification on pages 20-34 (response, page 16, 2nd and 3rd full paragraphs). However, the specification does not describe all mutant genes that confer the indicated traits. The specification also does not describe any maize plants having the introgressed gene, and which also have the morphological and physiological traits of PH51H described in Table 1. Further, claim 47 does not place any limitation at all on the mutant gene or transgene, or that trait(s) affected by it.

7. Claims 11-13, 22, 30, 47 and 52-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards maize plant PH51H, further comprising one or more mutant genes or transgenes; or a method of making a PH51H maize plant comprising introgressing a mutant gene or transgene.

The specification teaches that single gene conversions, or introgression, of the disclosed maize plant through traditional breeding is contemplated (page 20, lines 16-31). However, the specification does not teach any PH51H plants comprising single gene conversions. It is not clear that single genes may be introgressed into the genetic background of a plant through

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traditional breeding. Hunsperger et al. (U.S. Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant.

Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of single gene conversions taught in the prior art.

The specification teaches morphological and physiological traits expressed by inbred maize plant PH51H and that PH51H seed has been deposited with the ATCC (Table 1; page 50).

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The specification indicates that PH51H may be transformed with transgene(s), and provides examples of some particular transgenes known in the art (page 21, line 34 to page 34, line 2).

However, the specification does not enable transforming maize plant PH51H with all transgenes. As broadly interpreted, the method encompasses introducing any type of transgene into PH51H, including those that have not been isolated at the time the application was filed. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). Further, if the effect of transgene expression in PH3PG is unknown, one skilled in the art would not know how to use the transformed plant. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Furtherstill, the effects of transgene expression on the traits expressed by untransformed PH51H are unknown. The specification does not teach one how to use a transformed PH51H plant if all of the morphological and physiological traits of PH51H are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

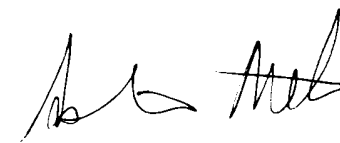
8. Claims 1-5, 7, 21, 23, 24, 26, and 40 are allowed. Claims 6, 9-16, 22, 25, 28-30, 34, 35, 37-39, 41, 42, 47, and 52-75 are rejected, and claims 8 and 27 are objected to.

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Contact Information

9. Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

August 18, 2003



Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638



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